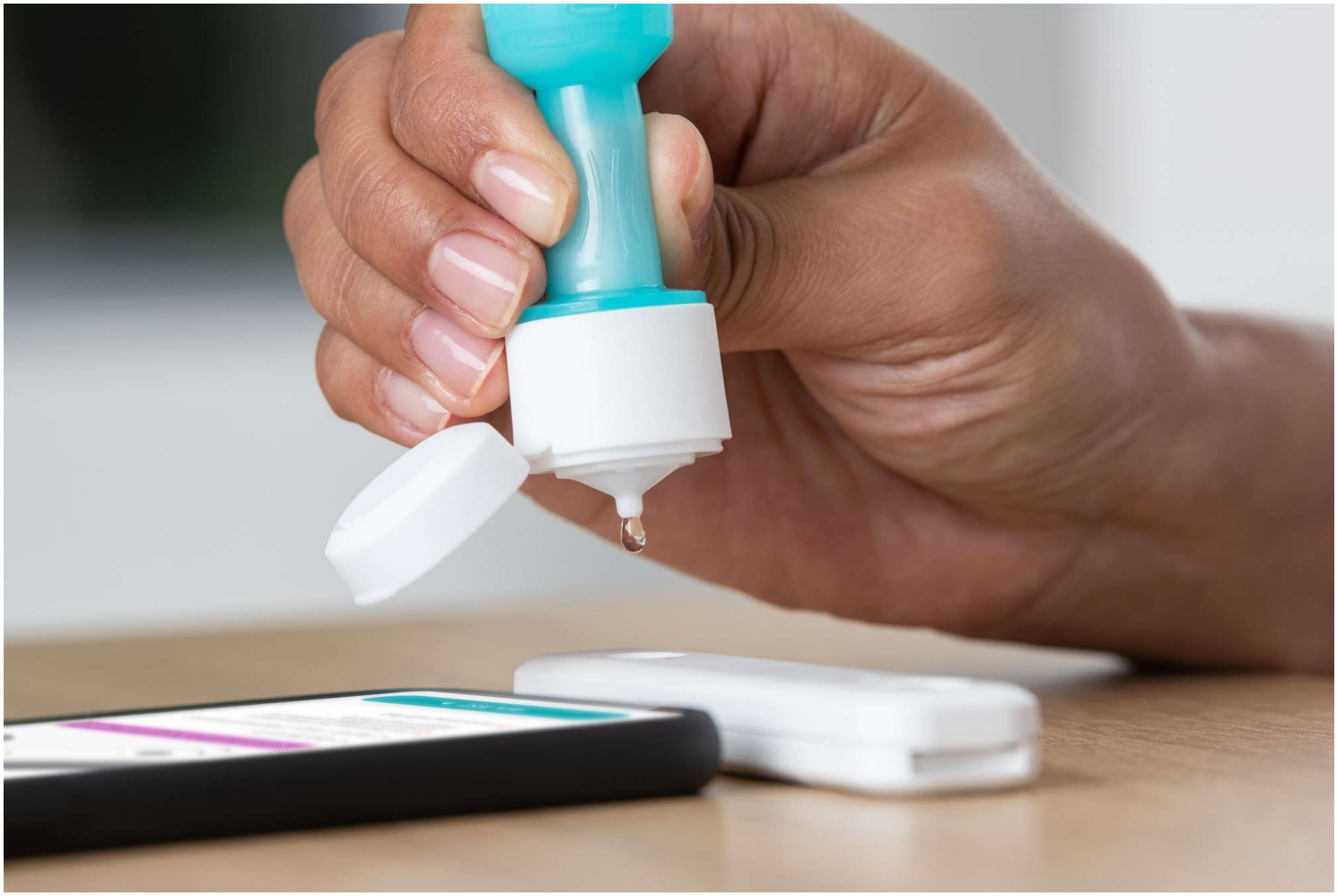
CORONAVIRUS

FDA authorizes first at-home, over-the-counter Covid test

The Australian digital diagnostics company Ellume said it expects to produce more than 3 million of the tests in January with a likely cost of $30 or less.



Ellume's self-administered rapid coronavirus test. Ellume via AP

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By Denise Chow

The Food and Drug Administration on Tuesday authorized the first test for Covid-19 that can be purchased at drug stores without a prescription and taken at home.

The test, developed by the Australian digital diagnostics company Ellume, received emergency use authorization from the FDA. The test does not require sending samples to a lab, similar to

how at-home pregnancy tests work.

The Ellume Covid-19 Home Test is an antigen test, which is designed to detect fragments of viral proteins that trigger an immune response in the body. Results are delivered via a smartphone app in as little as 20 minutes, according to the company.

The test involves collecting a sample with a nasal swab that users then place into a Bluetooth-connected analyzer that syncs with a smartphone app. Results are delivered through the app and can be shared with health care professionals, according to Ellume.

Ellume said it expects to produce more than 3 million of the tests in January with a likely cost of $30 or less. They will be available in pharmacies, drug stores and online, the company told NBC News in an email.

First Covid-19 vaccines begin in San Francisco

The at-home test correctly identified 96 percent of positive samples and 100 percent of negative samples in people with symptoms of Covid-19, the FDA said. In people who are not symptomatic, the test correctly identified 91 percent of positive samples and 96 percent of negative samples.

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Graphic: Coronavirus deaths in the U.S., per day

DATA GRAPHICS

These states have the most coronavirus cases. See the day-by-day breakdown.

Though antigen testing offers faster results and involves less lab work, they are not as sensitive as polymerase chain reaction, or PCR, testing, which has been the main method of screening for Covid-19. As such, antigen tests could deliver false negative results, in which a patient is infected but the antigen test is not sensitive enough to detect the viral proteins.

“This test, like other antigen tests, is less sensitive and less specific than typical molecular tests run in a lab,” Dr. Jeff Shuren, director of the FDA’s Center for Devices and Radiological Health, said in a statement. “However, the fact that it can be used completely at home and return results quickly means that it can play an important role in response to the pandemic.”

In its announcement about the emergency use authorization, the FDA said positive results from the Ellume test in people without symptoms “should be treated as presumptively positive until confirmed by another test as soon as possible.”

And since diagnostic tests can also deliver false negatives, the FDA recommended that any person who tests negative but experiences Covid-19-like symptoms should consult with their health care provider.

Denise Chow

Denise Chow is a reporter for NBC News Science focused on the environment and space.